



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,906	06/02/2000	KATY DRIEU	427.035	9289

7590 01/18/2002

CHARLES A MUSERLIAN
BIERMAN MUSERLIAN AND LUCAS
600 THIRD AVENUE
NEW YORK, NY 10016

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
----------	--------------

1651

DATE MAILED: 01/18/2002

//

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/555,906

Applicant(s)

DRIEU, KATY

Examiner

DR. Kailash C. Srivastava

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 December 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 17 October 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: Please see Attachment to Advisory Action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 2-8 and 10-13.

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

ATTACHMENT TO ADVISORY ACTION

1. The response filed December 17, 2001 (Paper Number 10) under 37 CFR 1.116 in reply to the final rejection mailed 07/17/2001 (Paper Number 8) has been considered but is not deemed to place the application in condition for allowance because: of the reasons of record on pages 2-3, item 6 of the Office Action Dated 07/17/2001 (Paper Number 8).

Lastly, the art rejections of record will be maintained. In response to this rejection, the applicant argues that the claimed invention would not have been obvious to an artisan of ordinary skill from the disclosure in the prior art references that the Examiner has cited. Argues further the applicant that, an artisan of ordinary skill would not have been motivated by the disclosures in the prior art that the examiner cites so as to combine them to successfully obtain the claimed invention. The applicant also argues that, "the combination is improper and requests withdrawal of grounds of rejections (Please see Page 3, Lines 23-24 of the response Document) that the Examiner has presented.

Applicant's arguments regarding the Prior art references in the reply filed on 12/07/2001 (Paper Number 10) have been fully considered in view of claims 2-8 and 10-13, but are not persuasive. The claims remain obvious for the following reasons:

A. Claim(s)

- teach a method to overcome withdrawal symptoms of substance dependency by administering an extract of *Ginkgo biloba* to ease withdrawal symptoms,
- 11 essentially reads on easing any symptoms of withdrawal,
- the substance being abused is anyone of alcohol, amphetamines or tobacco,
- the *Ginkgo* extract is comprised of ginkgolides A or B or acylated, alkoxylated or glycosylated ginkgolides, and
- the concentration of ginkgolides is up to 50%.

B. Among the cited References:

a. Remington's Pharmaceutical Sciences teaches:

- alcohol, amphetamines, cigarette (tobacco) smoke and other drugs may cause addiction,

- the symptoms of addiction are the same as those manifested upon withdrawal from addiction of above-mentioned drugs, wherein symptoms are (for e.g.): confusion, disorientation, headache, hallucination, insomnia, and nausea (Page 1291, Column 1, Para 1). Additionally cigarette smoking also renders cerebrovascular insufficiency.

b. The cited prior art (Hsia et al., Kleijnen et al., and Park et al.) teaches that *Ginkgo biloba* extract is comprised of:

- ginkgolides (Kleijnen et al., Page 1138, Column 1),
- methods to synthesize ginkgolide B derivatives (Park et al., Column 1, Lines 10-20, Column 4, Lines 20-39 and Lines 51-65) similar in structure to those recited in Claims 6-8 of instant invention,
- Park et al., disclose acetylated and alkoxyated ginkgolides.

c. Although, Park et al., and Kleijnen et al., do not disclose synthesis of glycosylated ginkgolides, from their teachings, an artisan of ordinary skill armed with the knowledge that at the time the claimed invention, methods to acetylate and alkoxyate ginkgolides were known, would have been motivated to synthesize glycosylated ginkgolides through substitution of mono-, di-, or polysaccharides to obtain the claimed glycosylated ginkgolides and subsequently incorporate the said synthesized glycosylated ginkgolides in the pharmaceutical composition that Kleijnen et al., disclose.

d. The cited prior art references (Hsia et al., and Kleijnen et al.) teach that:

- absent mindedness, confusion and headache are overcome with the administration of *Ginkgo biloba* extract (Hsia et al., Column 4, Lines 34-39),
- absent mindedness, anxiety, depression and dizziness and headache are treated with pharmaceuticals comprising *Ginkgo biloba* extracts (Kleijnen et al., Page 1136, Column 2, Lines 1-4).

Thus, the cited references show that at the time of the invention, it was well known in the art that ginkgo extract containing ginkgolides A and B or derivatives of ginkgolide B are useful in overcoming symptoms that are also manifested by an individual rehabilitating

from drug addiction. Based on the disclosure by Hsia et al., Kleijnen et al., and Park et al., that the ginkgo extract containing ginkgolides A and B, or derivatives of ginkgolide B referred in the cited references are used in pharmaceutical compositions to treat symptoms that are manifested by an individual undergoing drug addiction rehabilitation, an artisan of ordinary skill would have had a reasonable expectation that a combination of all these substances would also be useful to ease withdrawal symptoms in an individual undergoing drug addiction rehabilitation. Therefore, the artisan would have been motivated to combine all these components into a pharmaceutical preparation for the intended purpose.

Thus, applicant's arguments have been considered, however, these arguments are not persuasive because a showing to overcome a *prima facie* case of obviousness must be clear and convincing (*In re Lohr et al.*, 137 USPQ 548).

2. In sum, Claims 2-8 and 10-13 fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected under 35 U. S. C. § 103 (a).

3. No claims are allowed.


4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday, from 8:30 A.M. to 6:30 P.M. (Eastern Standard or Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

KCS
January 15, 2002


LEON B. LANFORD, JR.
PRIMARY EXAMINER